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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,045	08/31/2001	Masahiro Sasaki	188-88	7829

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,045	SASAKI ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-27,29-32,34-39 and 49-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27, 29-32, 34-39, 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/01/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission (amendment and declaration) filed on 30 March 2005 is acknowledged . Claims 21-25, 29, 31, 34, 36 have been amended, and claims 49-51 are new. Claims 21-27, 29-32, 34-39, and 49-51 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of rejection.

Claim Objections

The new claim 51 is objected to because of the following informalities: a single compound "calcium iron" does not appear to exist, therefore, a coma (,) after "calcium" in line 2 would be more appropriate for the ingredients being included in the composition. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 21-27, 29-32, and 34-39 **remain rejected**, and new claims **49-51 are also rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-27, 29-32, 34-39, and new claims 49-51 are under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Applicant argues that molecular weights based on atomic weights do not have units, so claims 21 and 31 constitute definitive recitation in this regard. This argument has been fully considered

but found unpersuasive. If the limitation "20,000" in claim 21, for example, is a molecular weight based on atomic mass units as applicant now argues, then, amending the claim to include "daltons" after "20,000" if such a support exists in the specification as originally filed would obviate this rejection. Note Voet et al., (Biochemistry, 1990, John Wiley & Sons, page 4 only) for molecular weight unit based on atomic mass units.

All other previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn either in view of amendment or applicant's persuasive arguments.

Claims 21-27, 29-32, and 34-39, and 49-51 **are newly rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claims 21, and 31 have a new limitation line 4, i.e. "extracted as a single protein from silk worm cocoons or raw silk", but it is not clear what the meets and bounds are. The specification at page 9, Preparation Examples 1, and 2 does not disclose the extracts being extracted as a single protein. It is not clear whether a single protein refers to purity or extraction method. If it refers to purity, then the purify of "90%" and "a single protein" in a single claim do not reconcile because "a single protein" implies there is nothing else but the protein but "90%" implies that there is other impurities. For the purpose of this Office action, the Office treats "90%" controls the scope of the claims. However, this treatment does not relieve applicant the burden of responding to this rejection.

Claims 21-27, 29-32, and 34-39 remain rejected and the new claims 49-51 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new matter rejection is maintained because of the new limitation "an average molecular weight range between 20,000 and 100,1000" in claims 49, and 50 and also the new limitation "at least 20,000" in base claims 21, and 31.

Applicant argues two preparation examples in the present application provide adequate support for this range. However, the specification as originally filed has support for making sericin of an average molecular weight of either 100,100 (see the last sentence of Preparation Example 1 at page 9), or 20,000 (see the last sentence of Preparation Example 2 at page 9).

As for the new limitation "at least 20,000" in base claims 21, and 31, MPEP 2163.05 has the following guidelines:

> With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement. See also Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("[T]he specification does not clearly disclose to the skilled artisan that the inventors... considered the... ratio to be part of their invention.... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion"). Compare Union Oil of Cal. v. Atlantic Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227, 1232-33 (Fed. Cir. 2000) (Description in terms of ranges of chemical properties which work in combination with ranges of other chemical properties to produce an automotive gasoline that reduces emissions was found to provide an adequate written description even though the exact chemical components of each combination were not disclosed and the specification did not disclose any distinct embodiments corresponding to any claim at issue.

"[T]he Patent Act and this court's case law require only sufficient description to show one of skill in the .. . art that the inventor possessed the claimed invention at the time of filing.").

The specification as originally filed does not have support for "at least 20,000", other than two points of an average molecular weight of either 100,100 or 20,000. Therefore, after consulting MPEP 2163.05, the Office concludes that the new limitation "at least 20,000" is a new matter.

The claims are also rejected for the limitation "extracted as a single protein". The Office is unable to find the support for this limitation.

Claim Rejections - 35 USC § 102

The rejection of claims 21-27, 29-32, and 34-39 under 35 U.S.C. **102(b)** as being anticipated by JP 1-256351 (I989, IDS) is **withdrawn** because the Office could not meet the burden that the composition of the prior art has purity of 90% or higher.

Claims **21-27, 29-31, 34, 36-39, remain rejected** and **new claims 49-50 are also rejected** under 35 U.S.C. **102(e)** as being anticipated by US Pat. 6,165,982 (Yamada et al).

Claims 21-27, 29-31, 34, 36-39, and 49-50 are drawn to composition suitable for oral administration comprising water-soluble, average molecular weight of 20,000 sericin with a purity of 90% or higher (base claims 21, and 31), wherein claim 22-26, 36, 38, and 39 list the effect, functional characteristics, and/or intended uses of the active ingredient of said sericin, wherein claim 27 lists an intended use i.e., "in the form of a health supplement", wherein claims 29 and 34 list the dose ranges of 1 mg to 1 g per kg

per body weight, wherein claim 30 and 37 list the source of sericin, and new claims 49 and 50 list the range of average molecular weight being 20,000 and 100,000.

Applicant argues that Yamada et al., fail to discloses "effective amount" of sericin to prevent colon cancer or any of the effective amounts enumerated in the various dependent claims.

This argument has been fully considered but found unpersuasive because the claims are interpreted as drawn to composition comprising sericin as the main active ingredient isolated from silkworm cocoons or raw silk and the intended use is not given patentable weight for purposes of comparing the claims with the prior art. The claims read on the composition *per se*, whose main ingredient is sericin mixture from silkworm cocoons or thread. Note the instant specification at pages 11-20; the effects and/or functional characteristics as listed in the instant claim 22-26, 36, 38, and 39 are due to the inherent characteristics of the active ingredient of said sericin,

As for argument with the limitation "dose form", the US Pat. 6,165,982 teach "The sericin or its hydrolyzate may be orally administered as medicines. In this instance, a dose is not particularly critical and it may be administered, for example, at a dose of about 10 mg.about.100 g/day", which encompasses the dose range in the instant claim 29. Further, the dose or the effective amount is not dosage or amount being administered to a patient in process claims but the composition is in such a way that it could be administered with such dosage. US Pat. 6,165,982 teaches composition suitable for oral administration comprising sericin derived from silkworm cocoons or raw

silk that meets instantly claimed limitation, i.e. the average molecular weight of 20,000 sericin with a purity of 90% or higher. See columns 4-6, and claims 4-15.

Thus, US Pat. 6,165,982 (Yamada et al) anticipates Claims 21-27, 29-31, 34, 36-39, and 49-50.

All other claims previously rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. 6,165,982 but not repeated in this Office action is withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D whose telephone number is 571-

272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D
Examiner
Art Unit 1642